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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,637	03/24/2004	Jun Feng	DPP-IV-5004-C2	8940
32793	7590	08/11/2006	EXAMINER	
TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			HABTE, KAHSA Y	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/809,637

Applicant(s)

FENG ET AL.

Examiner

Kahsay Habte

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1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/26/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-25, 27-29, 31, 33-73 and 75-86 is/are pending in the application.
- 4a) Of the above claim(s) 15-24, 33-57, 59-68, 72, 73 and 75-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 25, 27-29, 31, 58, 69-71 and 84-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/6/06, 9/14/05, 9/22/05 & 2/23/05
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-13, 15-25, 27-29, 31, 33-73, and 75-86 are pending in this application.

Claims 15-24, 33-57, 59-68, 72-73 and 75-83 are withdrawn from prosecution.

### ***Election/Restriction***

2. Applicant's election with traverse of Group I, Claims 1-13, 25, 27-29, 31, 58, 69-71 and 84-86 on 6/26/2006 is acknowledged. The traversal is on the ground(s) that "claim 1 is a genus claim (i.e. generic) that links the species of claims 2-86....

Accordingly, claim 1 is a linking claim that must be examined with the invention elected, and should claim be allowed, the restriction requirement must be withdrawn". The examiner disagrees with applicants. This is a restriction requirement between 20 groups that are different one from the other (see restriction requirement). Each groups comprises a different heterocyclic core system and classified in different classes and subclasses. Coexamination of each of the additional groups would require search of subclasses unnecessary for the examination of the elected claims. For example, the search for the invention of Group II would include search of subclass 544/12, the search for the invention of Group III would include search of subclass 544/279, and the search for the invention of Group VII would include search of subclass 544/256, etc. Therefore, coexamination of each of these additional inventions would require a serious additional burden of search.

The requirement is still deemed proper and is therefore made FINAL.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. Note that a "carbocyclic ring" is broader than a "benzo ring". It is required that applicants amend the claim from "carbocyclic" to "benzo" for the definition of R<sub>3</sub> and R<sub>4</sub>. It is also recommended that applicants recite specific substituents for variables R<sub>1</sub> and R<sub>2</sub>. Note that effective search can't be done because of the definitions of R<sub>1</sub> and R<sub>2</sub>.

***Information Disclosure Statement***

4. Applicant's Information Disclosure Statement, filed on 04/06/2006, 9/14/2005, 8/2/2005 and 2/23/2005 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-11, 13 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Kozhevnikov et al. Tr. Perm. Sel.-Khoz. Inst. (1971), No. 79, 66-72 From

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ref. Zh., Khim. 1972, Abstr. No. 9Zh404 Journal (English Abstract attached). Cited Russian article discloses seven quinazolinone compounds that are the same as applicants when applicants' Formula XXVIII has the following substituents:

$R_1$  = phenyl or substituted phenyl;  $UV = CH_2NH_2$ ; and  $R_3$  and  $R_4$  = unsubstituted benzo ring.

Note that some species are the same as claimed in claim 86.

The examiner has attached STN CAS online search printout that shows the prior art compounds.

6. Claims 1-8, 10-11, 13, 27, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenard et al. *J. Med. Chem.* **2001**, 44, 1710-1717. Cited reference at page 1711 discloses many quinazolinone compounds e.g. see compounds 6, 7, 10, 11-16 that are the same as applicants when applicants' Formula XXVIII has the following substituents:

$R_1$  = phenyl substituted with chloro;  $U = CH_2$ ;  $R_2 = CH_2-NH-CH_2$ -substituted phenyl; and  $R_3$  and  $R_4$  = fluoro substituted benzo ring.

7. Claims 1-8, 10-11, 13, 27, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Pattanaik et al. *Indian Journal of Chemistry, Section B; Organic Chemistry including Medicinal Chemistry* (1998), 37B (12), 1304-1306. Cited reference discloses many quinazolinone compounds that are the same as applicants when applicants' Formula XXVIII has the following substituents:

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$R_1$  = phenyl or phenyl substituted with chloro, methyl, methoxy;  $U = CH_2$ ;  $R_2$  = NH-substituted thiazolyl; and  $R_3$  and  $R_4$  = dibromo substituted benzo ring or unsubstituted benzo ring.

The examiner has attached STN CAS online search printout that shows the prior art compounds.

8. Claims 1-13, 27, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenard et al. EP 0900568 A2. Cited reference discloses many quinazolinone compounds at pages 2-3 that are the same as applicants when applicants' Formula XXVIII has the following substituents:

$R_1$  = phenyl or phenyl substituted with chloro,  $CF_3$  or pyridyl substituted with chloro, methyl;  $U = CH_2$ ;  $R_2$  = NH-substituted pyridyl or NH-substituted phenyl; and  $R_3$  and  $R_4$  = fluoro substituted benzo ring or unsubstituted benzo ring.

The examiner has attached STN CAS online search printout that shows the prior art compounds.

### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 15-25, 27-29, 31, 33-73 and 75-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent thereon are rejected because the term “substituted” is indefinite. In the absence of the specific moieties intended to effectuate modification by the “substitution” or attachment to the chemical core claimed, the term “substituted” renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

b. In claim 7 or elsewhere in the claims, the phrase “heteroaryl comprising a nitrogen ring atom” is an open-ended language. It is unclear what other heteroatoms are present in the ring. Also in claim 1 or elsewhere in the claims the term “comprising” is an open-ended language. Applicants have to delete this term to overcome the rejection.

c. In claim 1, the phrase “U is a moiety providing 1-6 atom separation” is indefinite. What is covered and what is not? It is recommended that applicants amend the claim as it was done in claim 4.

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d. In claim 1, the phrase "V comprises a basic nitrogen atom that is capable of interacting with a carboxylic acid chain of an active site residue of a protein" is not clear. How can one tell whether or not a basic nitrogen atom is capable of interacting with a carboxylic acid chain? What is covered and what is not? What is the nature of V? Is it a chain? A carbocyclic ring? A heterocyclic ring? It is recommended that applicants recite V to overcome this rejection. Note that claim 1 is unsearchable because of vague definitions of R<sub>1</sub> and R<sub>2</sub>.

e. In claim 25, the phrase "wherein the ring formed by J, K, L and M comprises substituents that form a ring fused to or bridged to the ring formed by J, K, L, and M" is not clear. What ring is formed? Do applicants intend a tricyclic ring? What substituents form a ring? It is recommended that applicants delete this claim. Note that Group I is drawn to quinazoline (bicyclic ring). The same problem appears in claims 84-85.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9.00- 5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone



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number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kahsay Habte', with a stylized, cursive script.

Kahsay Habte  
Primary Examiner  
Art Unit 1624

August 9, 2006